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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505T)

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DP BARCODE No.: D464380; **FILE SYMBOL/REG. No.**: 87373-RGU; **PRODUCT NAME:** ARG Cyfluthrin Technical; **DECISION No.**: 580449; **PC Code(s)**: 128831; **ACTION CODE**: R334; **FOOD Use**: Yes; **REGISTRANT**: ARGITE, LLC; **e-Submission # /Submission #**: 70236/1079088

DATE: January 20, 2023

SUBJECT: Summary of Product Chemistry Review of ARG Cyfluthrin Technical

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01-20-2023

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IVB1 / RD (7505T)

Product ingredient source information may be entitled to confidential treatment

Active Ingredient(s): Cyfluthrin 97%
Product label Claim : 97.0%

Proposed Basic CSF: Cyfluthrin 97% (Dated 10-20-2021; Upper limit = 99.90%; lower limit = 94.1%)
[Production site: [redacted]

MRID No(s).: Submitted – 51694001 - (830.1550, 830.1600, 830.1620, 830.1670 & 830.1750)
51694002 and 51694003 - (830.1700 & 830.1800 – Basic CSF)
51694004 (Group B data- Physical chemical properties).
51694005 – (Waiver requests Group B data)

INTRODUCTION

Pyxis Regulatory Consulting Incorporation on behalf of ARGITE, LLC has submitted an application for the registration of new technical product ARG Cyfluthrin Technical. The registrant has submitted a basic CSF dated 10-20-2021 supported by product chemistry data with MRID Nos. 51694001 to 51694005. The registrant has claimed that the proposed technical product is substantially similar to Baythroid Technical (Reg. No. 264-746).

CITAB has been asked to determine acceptability of the proposed basic CSF, the supporting product chemistry data submitted and determine similarity to the cited product.

Group A guidelines:

830.1550: (product identity & composition)

The active ingredient was adequately described (MRID 51694001). The nominal concentration of the active ingredient (97.0%) provided on the basic CSF (dated 10-20-2021) is the same as the average derived from the five-batch preliminary analysis results.

830.1600: (description of materials used to produce the product)

The specifications and suppliers of all the starting materials were provided in the study (MRID 51694001). Their Safety Data Sheets (SDSs) were provided. The information presented meet the data requirements for 40 CFR 158.325.

830.1620 (description of production process)

A detailed description of the production process, equipment, in process control measures and a flow chart were included in MRID 51694001. The information presented meets the data requirements for 40 CFR 158.330.

830.1670 (discussion on the formation of impurities)

Potential impurities were identified and quantified as part of the five-batch analysis (MRID 51694001). The information and identities of the impurities were fully discussed in MRID 51694002. The impurities associated to the active ingredient were found present at levels greater than 0.1%. The information presented meets the data requirements for 40 CFR 158.335.

830.1700 (preliminary analysis)

Results are presented for a five-batch analysis using HPLC-UV with external standard calibration for the active ingredient and significant impurities. All reference standards were certified. The identification for the Active Ingredient was performed by using LC-MS and FTIR. The identification for the Impurities were confirmed by using LC-MS and ^{1}H NMR. The information presented meets the data requirements for 40 CFR 158.345.

830.1750 (certified limits)

The proposed upper and lower certified limits for the active ingredient and all impurities on the proposed basic CSF (dated 10-20-2021) are within the range of the guideline OCSPP 830.1750 recommendation. The information presented meets the data requirements for 40 CFR 158.350.

830.1800: Enfocement Analytical Method

The methods for the determination of the active ingredient were validated with respect to linearity, specificity, system precision and repeatability the methods for the determination of the relevant impurities were validated. The validation was included with linearity, specificity repeatability, system precision, accuracy, limit of quantification and limit of detection. All methods are capable of determining whether an ingredient falls within its certified limits provided. The information presented meets the data requirements for 40 CFR 158.355.

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CONCLUSIONS:

Group A: Acceptable. All required data submitted to support the Basic CSF (Dated: 10-20-2021)

Group B: Acceptable

Group B (Waiver requests): Acceptable

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CSF:

Proposed Basic CSF (97%, dated 10-20-2021): Acceptable
[Production site: [redacted]

(5-batch analysis report on Page #18 of this report)

Alternate CSF in compliance with 40CFR§152.43: Yes []; No [ ]; NA [X]

Similarity to cited product with Reg. No.: 264-746 CSF dated 01-11-2005 Similar [X]; Not similar [ ]; Identical [ ]; Not applicable [ ]

Product label: Recommendations: Yes [X]; No []; NA [ ]

Note to PM: Since the product was found to be incompatible with oxidizing agents ($KMnO_4$), the registrant is recommended to add the following statement under Physical-Chemical Hazards on the product label:

"Do not mix or allow coming in contact with Oxidizing agents Reducing agents and organic solvents. Hazardous Chemical reaction may occur"

830.1550 (product identity & composition) [MRID No. 51694001]

Common Name: Clyfuthrin

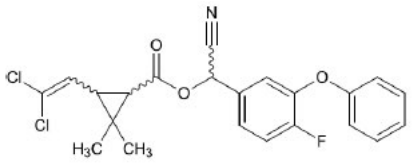
Chemical Name: cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate.

CAS No.: 68359-37-5

Molecular formula: $C_{22}H_{18}Cl_2FNO_3$

Molecular weight: 434.29

Structural formula:



Cyfluthrin

Product ingredient source information may be entitled to confidential treatment

Manufacturing facilities:

Basic CSF

[redacted]

Table 2: Physical and Chemical Properties for "ARG Cyfluthrin Technical"

CGLN	Requirement	MRID No	Status	Result or Deficiency
830.6302	Color	51694004	A	Light Yellow @ 25.2ºC
830.6303	Physical state	51694004	A	Oily, viscous mass with crystalline @ 25ºC
830.6304	Odor	51694004	A	Weak Pungent odor
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	51694004	A	TS was found to be stable in contact with metal/metal ions (Al, Cu and Fe metals and acetates of Fe & Cu) when placed in contact for 14 days at RT in term of AI contents. TS was found to be unstable in terms of AI contents when exposed to Fe, Al, Cu & corresponding acetates when exposed for 2 weeks at 54 C.
830.6314	Oxidation/reduction: chemical incompat bility	51694004	A	. TS was found to be compat ble with water, $NH_4H_2PO_4$, Fe powder and n-hexane but was non-compat ble with 0.1$KMnO_4$
830.6315	Flammability	51694005	W	Wavier request. Cyfluthrin does not contain combust ble liquids
830.6316	Explodability	51694005	W	Waiver request. Cyfluthrin does not have the chemical bonds or functional groups associated with explosive chemicals
830.6317	Accelerated storage stability	51694004	A	TS was found to be chemically & physically stable in commercial containers (HDPE lined steel drum) after storage for two at 54ºC with respect AI contents
830.6319	Misc bility	51694005	W	Wavier Request. Cyfluthrin Technical is not an emulsifiable liquid to be diluted with petroleum solvents
830.6320	Accelerated Corrosion characteristics	51694004	A	TS did not show any corrosiveness when stored for 2 weeks at 54ºC in commercial packaging (HDPE lined steel drum). The results revealed no significant change in physical or chemical property of the TS.
830.7000	pH	51694004	A	6.51
830.7050	UV/Vis ble absorption (TGAI)	51694004	A	pH = 6.53 61607 (L/mol·cm) at 192.75 nm pH = 1.87 54464 (L/mol·cm) at 197.15 nm pH = 11.81 44196 (L/mol·cm) at 199.62 nm
830.7100	Viscosity	51694005	W	Waiver Request. The product is a solid
830.7200	Melting point	51694004	A	42.6°C-46.6°C
830.7220	Boiling point	51694005	W	Waiver Request. Argite LLC is citing literature data for boing point of cyfluthrin. Cyfluthrin decompose before boiling
830.7300	Density	51694004	A	1.2763 g/cm^3
830.7370	Dissociation constants in water (DC)	51694005	W	Wavier Request. Cyfluthrin does not contain any functional groups that would dissociate

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CGLN	Requirement	MRID No	Status	Result or Deficiency
830.7550	Partition coefficient	51694005	W	Wavier Request. Argite, LLC citing public literature coefficient of cyfluthrin. The log P is 6 (20°C; ph7) Reference: Lewis, K.A., Tzilivakis, J., Warner, D. and Green, A. (2016). An international database for pesticide risk assessments and management. Human and Ecological Risk Assessment: An International Journal, 22(4), 1050-1064
830.7840	Solubility (in organic solvents)	51694005	W	Wavier Request. Argite, LLC is citing public literature data for the solvent solubility of cyfluthrin. The solubility (20°C) of cyfluthrin in water is 0.0066 mg/L; 200 g/L in xylene; 10 g/L in n-hexane; and 200 g/L in dichloromethane. Reference: Lewis, K.A., Tzilivakis, J., Warner, D. and Green, A. (2016). An international database for pesticide risk assessments and management. Human and Ecological Risk Assessment: An International Journal, 22(4), 1050-1064
830.7950	Vapor pressure	51694005	W	Waiver Request. Argite, LLC is citing public literature data for the vapor pressure of cyfluthrin. The vapor pressure at 20°C is 0.0003 mPa. Reference: Lewis, K.A., Tzilivakis, J., Warner, D. and Green, A. (2016). An international database for pesticide risk assessments and management. Human and Ecological Risk Assessment: An International Journal, 22(4), 1050-1064.

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress.
U = Up-grade (additional information required); W = waivers

CONFIDENTIAL APPENDIX

[redacted]

Manufacturing process

Pages 7-22 *Manufacturing process information may be entitled to confidential treatment*

CONFIDENTIAL APPENDIX

Pages 7-22 *Manufacturing process information may be entitled to confidential treatment*